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Proposed Maximum Residue Limit PMRL2015-44

Saflufenacil

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on wheat, barley and triticale to the product labels of HEAT® LQ and ERAGON® LQ, containing technical grade saflufenacil, is acceptable. The specific uses approved in Canada are detailed on the label of HEAT® LQ and ERAGON® LQ, *Pest Control Products Act Registration* Numbers 31468 and 31469, respectively.

The evaluation of this saflufenacil application indicated that the end-use product has value and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for saflufenacil is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Canada's Notification Authority and Enquiry Point.

The proposed MRLs, to replace or be added to the MRLs already established for saflufenacil, are as follows.

Table 1 Proposed Maximum Residue Limits for Saflufenacil

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Saflufenacil	2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl]-4-fluoro-*N*-[[methyl-(1-methylethyl)amino] sulfonyl]benzamide, including the metabolites *N*'-{2-chloro- 4-fluoro-5-[1,2,3,6-tetrahydro-2,6-dioxo-4-(trifluoromethyl)pyrimidin-1-yl]benzoyl}-*N*-isopropyl sulfamide , and *N*-[4-chloro-2-fluoro-5-({[(isopropylamino)sulfonyl]amino} carbonyl)phenyl]urea (all expressed in parent equivalents)	1.5	Barley bran
		1.0[2]	Barley
		0.6[2]	Triticale, wheat
		0.03[2]	Buckwheat, field corn, sweet corn plus cob with husks removed, pearl millet, proso millet, oats, popcorn grain, rice, rye, sorghum, teosinte, wild rice

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
	2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl]-4-fluoro-*N*-[[methyl-(1-methylethyl)amino]sulfonyl] benzamide	20	Meat byproducts of cattle, goats, horses, and sheep
		1.0	Meat byproducts of hogs
		0.02	Fat of cattle, goats, horses, and sheep
		0.01	Eggs; fat of hogs, and poultry; meat of cattle, goats, hogs, sheep, horses, and poultry; meat byproducts of poultry; milk

[1] ppm = parts per million

[2] The currently established MRL of 0.03 ppm in/on cereal grains (CG 15) will be replaced with specific MRLs of 0.03 ppm in/on buckwheat, field corn, sweet corn plus cob with husks removed, pearl millet, proso millet, oats, popcorn grain, rice, rye, sorghum, teosinte, wild rice; 1.0 ppm in/on barley; and 0.6 ppm in/on triticale and wheat, to reflect the new use pattern on barley, triticale and wheat as pre-harvest weed management.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data. For livestock commodities, differences in MRLs can also be due to different livestock feed items and practices.

The MRLs proposed for saflufenacil in Canada are the same as the corresponding American tolerance as listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Table 2 compares the MRLs proposed for saflufenacil in Canada with corresponding Codex MRLs.[1] A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food website, by pesticide or commodity.

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Table 2 Comparison of Canadian MRLs and Codex MRLs (where different)

Food Commodity	Canadian MRL (ppm)	Codex MRL (ppm)
Barley bran	1.5	0.01 (cereal grains)
Barley	1.0	
Triticale, wheat	0.6	
Buckwheat, field corn, sweet corn plus cob with husks removed, pearl millet, proso millet, oats, popcorn grain, rice, rye, sorghum, teosinte, wild rice	0.03	

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for saflufenacil up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

Appendix I

Summary of Field Trial Data Used to Support the Proposed MRLs

To support the change in formulation of HEAT® and ERAGON® from a water soluble granule (WG) to a suspension concentrate (SC), previously reviewed residue data were reassessed in the framework of these petitions:

- pre-plant or pre-emergent applications: barley, corn (sweet, field), rice, sorghum, wheat, pea (succulent, dry), dry bean, soybean (succulent, dry);
- late season applications for harvest aid/dessicant use : dry bean, dry pea, dry soybean, sunflower and canola.

To support the domestic use of HEAT® LQ and ERAGON® LQ as a pre-harvest weed management treatment on wheat (spring, winter, durum), barley (spring, winter, malting) and triticale, residue data from field trials conducted in Canada and the United States were submitted. Saflufenacil was applied to wheat and barley at one- to 1.6-fold approved rates, and harvested according to label directions. Data on wheat were extended to triticale. In addition, processing studies in treated wheat and barley were reviewed to determine the potential for concentration of residues of saflufenacil and metabolites M800H11 and M800H35 into processed commodities.

Maximum Residue Limit(s)

The recommendation for maximum residue limits (MRLs) for saflufenacil were based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs for barley, triticale and wheat.

Table A1 Summary of Field Trial and Processing Data Used to Support Maximum Residue Limit(s) (MRLs)

Commodity	Application Method/Total Application Rate (g ai/ha)[1]	Preharvest Interval (days)	Combined Residues[2] (ppm)		Experimental Processing Factors[3]
			min	max	
Wheat (grain) extended to triticale (grain)	Broadcast foliar application/48-52	2-3	<0.03	0.68	Bran: saflufenacil: 1.25 M800H11: 1.0 M800H35: 1.0
Barley (grain)	Broadcast foliar application/48.1-81.1	2-3	0.06	0.58	Bran: saflufenacil: 2.94 M800H11: 1.0 M800H35: 1.0

[1] g ai/ha = grams of active ingredient per hectare
[2] Combined residues are the sum of saflufenacil, M800H11 and M800H35 (all expressed in parent equivalents).
[3] Experimental processing factors were calculated individually for saflufenacil, M800H11 and M800H35.

Based on the dietary burden and residue data, MRLs of 20 ppm in meat byproducts of cattle, goats, horses, and sheep; 1.0 ppm in meat byproducts of hogs; 0.02 ppm in fat of cattle, goats, horses, and sheep; 0.01 ppm in eggs, fat of hogs and poultry, meat of cattle, goats, horses, sheep, hogs and poultry, meat byproducts of poultry and milk to cover residues of saflufenacil are also proposed.

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover total residues of saflufenacil, M800H11 and M800H35 (expressed in parent equivalents). Residues in these crop/livestock commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.